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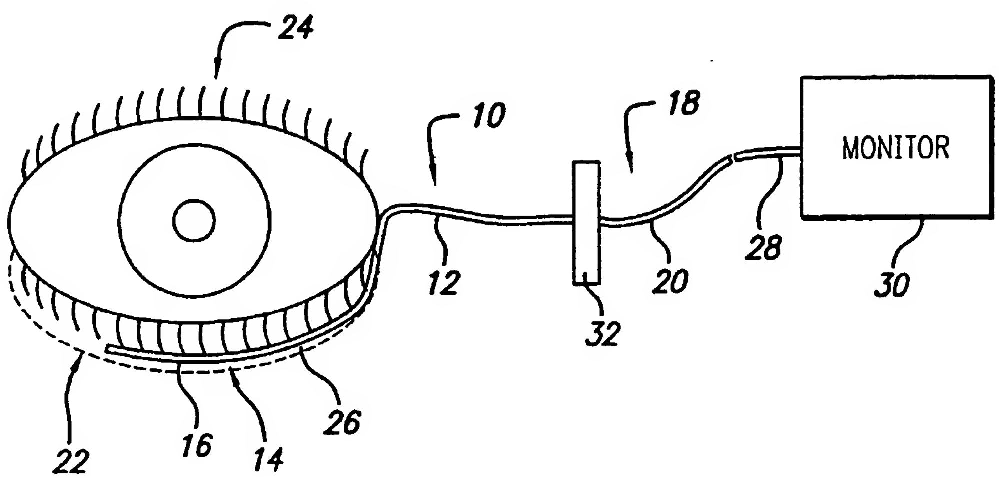
(54) Title: METHOD OF MONITORING CONJUNCTIVAL SYSTEMIC PARAMETERS



(57) Abstract: The method of non-invasively measuring multiple systemic and tissue parameters from the conjunctiva can be applied to neonates and adults, with minimal risk of discomfort or damage to a patient's eye. The method involves providing a tissue parameter catheter sensor (10) for sensing one or more parameters of a patient's tissue, inserting the distal portion (14) of the tissue parameter catheter sensor in the fornix of a patient's eye (22) in immediate contact with the conjuctiva of the patient's eye (26), receiving the signal indicative of one or more parameters, and displaying an indication of one or more of the parameters (30) based upon a signal from the tissue parameter catheter sensor. The tissue parameter catheter sensor includes multiple individual sensors for monitoring parameters of a patient's tissue, such as tissue pH, and tissue levels of oxygen and carbon dioxide.

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METHOD OF MONITORING CONJUNCTIVAL SYSTEMIC PARAMETERS

BACKGROUND OF THE INVENTION

Field of the Invention:

This invention relates generally to blood and systemic tissue parameter sensors, and more particularly concerns a method of monitoring systemic and tissue parameters such as tension of oxygen, CO_2 and pH of body tissues from the conjunctiva.

Description of Related Art:

Monitoring of systemic and blood parameters such as the partial pressure or tension of oxygen, CO_2 and pH of the blood typically forms an essential part of the care of critically ill patients. A conventional method of measuring such parameters is by withdrawing blood from the patient for analysis in a blood gas analyzer. However, difficulties can be encountered in withdrawing sufficient blood on a regular basis from critically ill adult patients, children, and neonates such as premature infants.

One alternative to withdrawing blood for analysis is the development of a blood sensor, such as an oxygen sensor, that can be introduced directly into blood vessels of a patient for determining the partial pressure of oxygen in the blood of the patient. In one blood oxygen sensor, a pair of electrodes are provided in an electrolyte in a chamber of a plastic flexible tube that is permeable to oxygen. The electrodes project into the chamber at two different distances to be in contact with the electrolyte, with an insulating layer provided on the longer wire in a region adjacent to the shorter wire.

A multi-parameter blood sensor is also known, having multiple

individual sensors in a catheter that is also directly introduced into a patient's blood vessel. The catheter is formed from a microporous biphasic membrane filled with a hydrophilic material forming a gel and allowing the passage of water-bound ions to individual sensors, for use in measuring pH, pO_2, pCO_2, and temperature of a patient's blood. However, problems can also be encountered in introducing such invasive devices into a patient's blood vessel, particularly when the blood vessels are extremely small or in poor condition, so that it would also be desirable to provide a method for non-invasively monitoring the blood parameters of patients.

Transcutaneous oxygen sensors offer a commonly used method of non-invasively monitoring oxygen blood levels. However, this technology suffers from induction of errors due to insufficient vasodilation, which can be affected by temperature, so that external heating can be required. In addition, errors can be caused by inadequate or changing contact with the surface of the skin, which can be affected by external factors such as patient movement. The heating element often leaves marks on the skin, and can even burn the patient.

Pulse oximetry measures oxygen through the skin. The modality it specifically determines is the percent saturation of hemoglobin by oxygen. Unfortunately, the instrument will read 99 to 100% saturation when the blood oxygen tension reaches about 100 mg Hg or above. Even if the blood reading increases to 200 mg Hg or beyond, the pulse oximeter will continue to read 99 to 100%. This can lead to oxygen toxicity, or in newborns, to retinopathy of prematurity with possible blindness.

Transconjunctival oxygen monitors offer the advantage of sensing the oxygen tension in the tissue bed of the conjunctiva of the eye that is vascularized by the internal carotid artery, and which thus reflects intracranial oxygenation levels. The vessels of the conjunctiva are covered by a very thin mucous membrane epithelium, so that it is possible to obtain an accurate indication of blood characteristics by placement of a sensor against the conjunctiva. External heating of the tissue is unnecessary, and

adequate contact with the tissue of the palpebral conjunctiva is not commonly a problem. Tissue parameters can also better represent the internal milieu of the person and are reflective of tissue perfusion. The eye is important in this respect because the eye is said to be the window to the brain, and in a sick individual the brain can be the most important organ to be perfused. In addition, in sick neonates, this type of tissue parameter monitoring may be useful in preventing retinopathy, a degenerative disease of the retina, which is a concern in cases of prematurity.

One such conjunctival sensor is known for detecting the tension of oxygen from the palpebral conjunctiva of a patient. The sensor includes a conformer ring locating body having a concave face adapted to conform to the sclera of the eye, a convex face adapted to contact the palpebral conjunctiva, and an open portion in the center adapted to be away from the cornea. The locating body includes an electrochemical detector portion with a platinum cathode and a silver-silver reference anode, with electrical leads leading from the electrode through the conformer ring locating body and to a monitor. The locating body also includes a thermistor for measuring the temperature at the palpebral conjunctiva. However, practitioners have been hesitant in applying the sensor to adult patients or neonates, due to the risk of damaging the surface of the eye, and particularly for neonates such as premature infants because their eyes are smaller and more delicate than those of an adult, and because the infants' eyes can grow rapidly. A need therefore continues to exist for a type of blood parameter sensor that can be easily accommodated in the conjunctival area of the eye with minimal risk of discomfort or damage to the eye. The present invention meets these and other needs.

SUMMARY OF THE INVENTION

Briefly, and in general terms, the present invention provides for a method of non-invasively measuring multiple systemic and tissue parameters from the

conjunctiva in a manner that can be applied to neonates and adults alike, with minimal risk of discomfort or damage to a patient's eye.

Accordingly the present invention provides for a method of measuring at least one parameter of a patient's tissue. The method comprises the steps of providing a tissue parameter catheter sensor for sensing at least one parameter of a patient's tissue, the tissue parameter catheter sensor generating a signal indicative of one or more tissue parameters, inserting the distal portion of the tissue parameter catheter sensor in the fornix of a patient's eye in immediate contact with the conjunctiva of the patient's eye, receiving the signal indicative of at least one parameter, and displaying an indication of at least one parameter based upon the signal from the sensor. The tissue parameter sensing catheter preferably includes an elongated tube or sheath having a distal portion with at least one sensor for measuring at least one parameter of a patient's tissue; however, in one presently preferred embodiment, the tissue parameter catheter sensor includes a plurality of individual sensors to sense a plurality of parameters of a patient's tissue, such as tissue pH, and tissue levels of oxygen and carbon dioxide.

These and other aspects and advantages of the invention will become apparent from the following detailed description and the accompanying drawing, which illustrates by way of example the features of the invention.

BRIEF DESCRIPTION OF THE DRAWING

Figure 1 is a schematic diagram of the method of the invention showing placement of a tissue parameter catheter sensor in the lower fornix of a patient's eye in immediate contact with the conjunctiva of the patient's eye for sensing one or more tissue parameters of a patient;

Fig. 2 is a graph illustrating the monitoring tissue parameters of pCO2 and pO2 in the conjunctiva of a pig during an experiment;

Fig. 3 is a graph illustrating the monitoring tissue parameters of pCO2 and pO2 in the conjunctiva of a pig during another experiment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Conventional methods for monitoring systemic and tissue parameters such as tension of oxygen, CO_2 and pH for critically ill adult patients and neonates can be problematic. While invasive multi-parameter blood sensors can provide this information, traditional transcutaneous non-invasive methods of measuring these blood parameters can be unreliable, and conventional forms of transconjunctival oxygen monitors have required that a conformer ring be placed on the sclera of the eye.

As is illustrated in Figure 1, the invention is accordingly embodied in a method of measuring one or more parameters of tissue of a patient. In a currently preferred embodiment, a tissue parameter catheter sensor for sensing one or more parameters of a patient's tissue is provided that includes an elongated tube or sheath having a distal portion with at least one sensor that measures one or more parameters of a patient's tissue, and that generates signals indicative of one or more of a plurality of parameters of a patient's tissue, such as oxygen, CO_2, pH, and temperature. One such currently preferred multi-parameter catheter sensor that can be modified for use according to the method of the invention is available under the trade names "PARATREND" and "NEOTREND" from Diametrics Medical Inc. and Agilent Technologies, and which is described more fully in U.S. Patent No. 5,596,988, which is incorporated herein by reference.

The multi-parameter catheter sensor 10 comprises a hollow sheath 12 having a distal portion 14 terminating in a distal end that is sealed to form a closed chamber for individual sensors. The wall 16 of the hollow sheath is formed from a microporous, hydrophobic thermoplastic material, such as high density polyethylene. A proximal portion 18 of the multi-parameter catheter sensor is covered by a protective

cover 20 that is trimmed away, to leave a greater length of the microporous, hydrophobic polyethylene sheath exposed for placement of the distal portion of the tissue parameter catheter sensor in the lower fornix 22 of a patient's eye 24 in immediate contact with the conjunctiva 26, such as the palpebral conjunctiva, of the patient's eye, although the sensor may extend to either the upper or lower fornix.

The proximal portion of the multi-parameter catheter sensor also has an output lead 28 that comprises a wire from the temperature sensor and optical fibers from the individual oxygen, CO_2, and pH sensors leading to a monitor unit 30 receiving signals from the individual sensors indicative of the parameters being monitored, and displaying the results based upon the signals received. The output lead of the multi-parameter catheter sensor can be taped 32 to the skin outside the eye of the patient. For tenuous premature babies, as well as adults and children, the device can thus monitor tissue parameters from the patient's eyes and provide useful information concerning their systemic status.

Example 1 - Sheep Study:

A Paratrend 7 (TM) sensor available from Diametrics Medical Limited was inserted into a 45 kg pregnant sheep at 11:31, with initial insertion in the lower fornix providing readings of pH 7.05, pCO_2 50.9, and pO_2 38; insertion in the upper fornix providing readings of pH 6.93, pCO_2 50.0, and pO_2 26; insertion with the eye open providing readings of pH 6.93, pCO_2 53. 1, and pO_2 111; and insertion with the eye closed providing reading of $pO_2 < 60$. Arterial blood gases (ABG) provided blood gas readings of 7.41/40.3/444 vs. 6.61/43.4/127; ABG at 12:45 provided readings of 6.87/54.7/81. Monitoring ended at 15:19. The results of the testing are presented in Table 1 below.

Time	pH	pCO_2	pO_2	Comments
11:42	7.41	22.2	179	
11:44	7.19	29.8	88	
11:46	7.08	44.2	56	
11:51	7.08	51.5	27	
11:55	7.20	35.0	106	catheter came out
11:59	6.96	46.0	30	
12:02	6.93	49.5	26	
12:01	6.92	50.3	25	
12:11	6.91	52.0	23	eye opened
12:13	6.89	53.0	110	
12:14	6.90	53.2	111	
12:16	6.90	53.7	110	eye retaped
12:18	6.94	53.3	59	
12:19	6.95	53.8	100	maternal ABG 735/47.5/152.3
12:21	6.93	54.6	107	
12:30	6.91	53.3	91	R a
12:35	6.90	52.8	84	
12:37	6.90	53.5	80	
12:43	6.88	54.7	75	ABG 7.37/ 43/76.8
12:48	6.86	54.4	68	
12:49	6.86	52.8	80	
12:53	6.86	51.4	69	
12:54	6.86	50.8	90	
12:50	6.89	50.1	89	FINAL

Table 1: Sheep Experiment 1

Example 2 - Sheep Study:

An 8 cm Paratrend 7 (TM) sensor as described above was inserted in the upper fornix of the left eye of a 45 kg sheep with the eye open, and pulled to 6 cm. The results of the testing are presented in Table 2 below.

Time	pH	pCO_2	pO_2	Comments
13:20	7.24	37	43	21 % ABG 7.37/ 36.9/ 79/ 21
13:28	7.23	39.9	40	
13:22	7.23	38.6	40	
13:23	7.23	39.3	40	
13:24	7.23	39.9	40	
13:29	7.23	39.6	36	
13:28	7.23	39.5	40	
13:27	7.23	39	39	
13:28	7.23	38.6	38	
13:29	7.23	38.4	37	
13:31	7.22	38.7	37	
13:33	7.21	38.5	37	
13:34	7.2	38.7	36	
13:36	7.19	38.6	36	
13:37	7.16	39.2	36	
13:38	7.14	39.3	37	

13:39	7.14	39.4	39	
13:40	7.13	39.4	38	Fi02 15%
13:41	7.14	39.3	38	
13:42	7.14	38.9	36	ABG 7.35/38/80/21
13:43	7.14	38.6	35	
13:44	7.14	38.8	34	
13:45	7.14	38.3	34	
13:46	7.14	38.3	33	
13:47	7.13	38.1	33	
13:48	7.13	37.9	33	
13:49	7.12	37.9	33	
13:50	7.12	37.9	33	
13:51	7.12	37.8	33	
13:52	7.12	37.8	33	
13:53	7.11	37.6	33	
13:54	7.1	37.4	32	
13:55	7.1	37.4	33	
13:56	7.09	37.4	33	
13:57	7.08	37.3	33	
13:58	7.07	37.1	32	
13:59	7.06	37.3	32	
14:00	7.05	37.1	32	
14:01	7.04	37.2	32	
14:02	7.03	37.3	32	
14:03	7.03	37	32	
14:04	7.02	37	32	
14:05	7.01	37	32	

14:06	7.01	37	32	
14:07	7	37.1	32	
14:08	6.99	36.9	32	
14:09	6.99	36.8	31	
14:10	6.97	37.7	31	
14:11	6.97	38.2	31	
14:12	6.97	38.5	31	
14:13	6.97	39.5	30	
14:14	6.97	39.8	29	
14:15	6.96	40	28	
14:16	6.95	40.8	26	
14:17	6.94	41.3	25	
14:18	6.93	41.8	25	
14:19	6.94	41.6	27	Fi02 12%
14:20	6.95	40.4	29	
14:21	6.95	39.2	27	
14:22	6.95	38.6	26	
14:23	6.94	38.4	26	
14:24	6.93	38.2	26	
14:25	6.92	38.3	26	
14:26	6.91	38.2	26	
14:27	6.91	37.9	26	
14:28	6.9	37.9	26	
14:29	6.9	37.8	26	
14:30	6.9	37.7	26	
14:31	6.89	37.7	21	
14:32	6.88	37.5	27	
14:33	6.87	37.4	27	

14:34	6.87	37.2	26	
14:35	6.86	37.3	25	
14:36	6.85	37.2	25	
14:37	6.85	37	25	
14:38	6.84	36.9	24	
14:39	6.83	36.7	24	
14:40	6.83	36.8	23	
14:41	6.81	36.8	23	
14:42	6.79	37	23	
14:43	6.78	37.4	25	
14:44	6.77	37.6	26	
14:45	6.76	37.6	27	
14:46	6.75	38.1	27	
14:47	6.75	37.8	28	
14:48	6.74	37.5	28	
14:49	6.73	37.5	28	
14:50	6.72	37.5	28	
14:51	6.7	37.2	28	
14:52	6.69	37.1	27	
14:53	6.7	37.1	27	
14:54	6.68	37.2	27	
14:55	6.67	37.1	27	
14:56	6.66	37.2	27	
14:57	6.66	37.2	27	
14:58	6.64	37.1	27	
14:59	6.64	37	27	
15:00	6.63	37.2	27	
15:01	6.61	36.9	27	

15:02	6.61	36.8	27	
15:03	6.61	37	27	
15:04	6.6	36.8	27	
15:05	6.59	36.5	27	
15:06	6.58	36.5	27	
15:07	6.58	36.2	27	
15:08	6.57	36.2	26	
15:09	6.57	36.1	27	
15:10	6.57	36.3	27	
15:11	6.57	36.2	26	
15:12	6.56	5.9	26	
15:13	6.55	35.9	25	
15:14	6.54	35.6	25	
15:15	6.54	35.7	24	Fi02 10%
15:16	6.54	35.4	24	
15:17	6.53	35.4	24	
15:18	6.52	35.3	24	
15:19	6.52	35.2	24	
15:20	6.53	35.4	24	
15:21	6.55	35.1	24	
15:22	6.55	34.9	24	
15:23	6.54	34.8	24	
15:24	6.52	34.7	24	

Table 2: Sheep Experiment 2

Example 3 - Sheep Study:

A Paratrend 7 (TM) sensor having a total length of 60 cm. was inserted as described above in the left eye superior fornix of a 55 kg sheep, and oxygen flow was delivered to the sheep at 4.5 liter/min. The results of the testing are presented in Table 3 below.

Time	pH	pCO_2	pO_2	Comments
15:08				Sensor inserted
15:08	6.6	18.3	119	
15:09	6.66	16	77	
15:10	6.8	13	64	
15:11	6.78	14.7	63	
15:12	6.76	16.9	65	
15:15	6.72	20.7	65	
15:17	6.72	21.4	61	
15:19	6.7	21.3	59.0	
15:19	6.68	21.5	57	
15:20	6.66	21.1	56	
15:22	6.65	20.9	56	
15:23	6.65	20.7	65	
15:24	6.66	20.6	55	
15:25	6.66	20.6	54	
15:26	6.64	20.9	54	
15:27	6.64	19.8	53	
15:29	6.64	17.7	54	
15:30	6.64	19.2	55	
15:31	6.64	19.1	55	
15:32	6.64	18.2	56	

15.33	6.63	18.4	57	
15:34	6.64	19	57	
15:35	6.65	18.4	58	
15:36	6.64	18	58	
15:37	6.64	16.5	57	
15:38	6.63	14.2	53	
15:39	6.63	14.8	51	
15:40	6.64	15.1	51	
15:41	6.66	14.7	50	
15:42	6.66	15.1	50	
15:43	6.66	15.1	50	
15:44	6.67	14.9	51	
15:45	6.67	15.1	51	Sat 46. 1 %
15:46	6.67	15.1	51	
15:47	6.66	15.3	51	
15.48	6.66	15.3	51	
15:49	6.66	15.3	52	
15:50	6.65	15.3	53	
15:51	6.66	15.2	52	Sat 48.2%
15:52	6.66	16.3	53	
15.53	6.67	16.6	54	
15:54	6.67	16.5	55	
15:55	6.67	15.6	55	
15:56	6.67	16.1	56	
15:57	6.67	16.4	56	
15:58	6.67	16.8	57	
15:59	6.68	16.6	57	
16:00	6.68	12.7	57	

16:00	16.68	10.4	56	
16:02	6.68	12.3	55	Sat 50.0%
16:03	6.67	12.7	53	
16:04	6.66	14.3	52	Sat 47%
16:05	6.65	15.3	52	
16:06	6.64	15.3	53	
16:07	6.62	16.3	54	
16:08	6.62	16.4	54	
16:09	6.62	16.4	55	Sat 47.1 %
16:10	6.61	14.8	55	

Table 3: Sheep Experiment 3

Example 4 - Pig Bleeding Study:

A 7 cm Paratrend (TM) sensor was inserted in a 44 kg pig's eye, which is much smaller than the sheep eye, and the sensor was subject to multiple kinking. Bleeding of the pig was initiated, and the tissue parameters were monitored, with the sensor results as shown in Table 4 below, and in Fig. 2.

Time	pH	pCO_2	pO_2	Comments
12:36				sensor placed
1:37	5.99	24.8	233	
				sensor manipulated ABG 7.36/49/616
1:45	5.99	34.9	195	

1:43	5.99	23.8	195	
1:44	5.99	19.1	195	
1:45	5.99	17.6	175	
1:46	5.99	17	175	Saline injection
1:47	5.99	17	176	
1:48	5.99	17.1	175	
1:49	5.99	17.3	176	15 % bleed
1:50	5.99	13	175	800 cc
1:51	5.99	17.1	174	
1:52	5.99	17.4	173	
1:53	5.99	17.4	183	
1:54	5.99	22.7	194	
1:55	5.99	43.1	194	
1:56	5.99	53.1	197	
1:57	5.99	56.3	185	700 cc
1:58	5.99	77.7	172	
1:59	5.99	58.1	70	
2:00	5.99	58.1	167	
2:01	5.99	58.2	185	350 cc. -800 total
2:02	5.99	57.6	165	
2:03	5.99	57.7	164	
2:04	5.99	58	168	BP 42/35
2:05	5.99	58.1	168	
2.06	5.99	57.9	149	
2:07	5.99	56.2	93	
2:08	5.99	55.9	53	

2:09	5.99	55.6	38	
2:10	5.99	55.4	24	
2:11	5.99	55.5	13	
2:12	5.99	56	11	
2:13	5.99	56.5	13	HR 160
2:14	5.99	56.5	13	
2:15		56	7	15 Animal moved
2:17		57	5	15
2:18		63	4	
2:19				
2:20				
2:30				Animal allowed to waken. Sensor non-functional
2:44				Unable to resume sensor kinked study terminated

Table 4: Pig Experiment 1

Example 5 - Pig Bleeding Study:

A Paratrend (TM) sensor was inserted in the lower fornix of a 42.7 kg pig's right eye. At the outset, the heart rate of the pig was 154, and the blood

pressure was 67/36. Bleeding of the pig was initiated, and the tissue parameters were monitored, with the sensor results as shown in Table 5 below.

Time	pH	pCO_2	pO_2	Comments
12:24				ABG 7.45/32/526
12:25	7.13	36	168	
12:27	7.09	44	166	
12:28	7.08	49	167	
12:29	7.06	51	169	
12:30	7.06	53	168	
12:31	7.0[illegible]	56	169	
12:33	7.03	57	169	
12:35	7.01	57	169	
12:37	7.01	58	170	
12:39	7.00	59	169	
12:40	6.99	59	168	
12:42	6.99	59	168	
12:44	6.98	59	169	
12:46	6.98	59	168	
12:48	6.98	60	168	
12:50	6.97	59	167	
12:53	6.97	59	167	
12:54	6.95	59	167	
12:55	6.96	59	167	

12:56	6.95	59	166	ABG. 7.35 /37/509
12:57	6.95	60	163	
12:59	6.93	61	162	
13:00	6.91	63	162	
13:02	6.91	64	160	800 cc
13:04	6.91	64	160	
13:06	6.90	65	157	
13:07	6.89	65	158	900 cc
13:08	6.89	65	159	
13:10	6.89	65	159	
13:12	6.89	65	157	
13:12	6.89	65	156	1300 cc
13:15	6.87	65	157	
13:16	6.87	65	156	250cc more
13:17	6.87	65	156	
13:19	6.87	64	156	
13:21	6.86	64	155	
13:23	6.86	64	155	
13:24	6.85	63	156	200 cc more
13:25	6.85	62	156	1800 cc
13:27	6.86	62	156	
13:29	6.85	62	156	HR 123 bp 102/59
13:30	6.85	62	155	
13:32	6.84	61	156	
13:35	6.84	61	156	
13:37	6.84	60	158	

13:39	6.94	61	157	HR 177 Bp 99/ 57
13:41	6.83	60	157	
13:43	6.84	61	158	
13:45	6.84	61	158	
13:47	6.84	58	158	
13:49	6.84	58	157	
13:51	6.84	56	159	
13:53	6.84	57	158	
13:55	6.84	57	158	
13:57	6.82	57	159	
13:59	6.82	57	158	
14:01	6.82	56	158	
14:05	6.80	56	158	
14:09	6.80	55	158	HR 160 BP 89/46
14:12	6.80	54	158	
14:15	6.80	53	156	
14:18	6.79	52	156	
14:23	6.77	51	155	HR 115 BP 98/53
14:27	6.76	53	156	
14:32	6.74	54	156	800 cc/15 min
14:34	6.73	54	155	
14:36	6.73	55	154	
14:38	6.72	55	153	
14:40	6.72	55	152	

14:42	6.72	55	150	HR 112 BP123/68
14:45	6.71	55	149	
14:46	6.71	55	151	
14:48	6.70	55	149	BP 121/69
14:50	6.70	55	150	2500 cc Total
14:52	6.68	55	149	
14:54	6.68	56	150	
14:57	6.69	56	150	
14:59	6.69	56	149	
15:04	6.68	56	148	
15:07	6.67	57	148	

Table 5: Pig Experiment 2

Example 6 - ECMO Study:

ECMO (Extracorporeal Membrane Oxygenation) was administered to a pig, and a Paratrend (TM) sensor was inserted in the upper fornix of the pig's left eye, with the sensor results as shown in Table 6 below, and in Fig. 3.

Time	pH	pCO_2	pO_2	Comments, Blood Gases Arterial, Venous
9:42				sensor placed
9:47	6.8	57	68	A 7.36/48/201 V 7.38/50/68

9:50	6.78	57	71	A 7.36/481201 V 7.38/50/69
9:54	6.72	56	59	A 7.38/47/202 V 7.39/49/64
10:02	6.45	59	93	A 7.47/39/212 V 7.41/48/60
10:05	6.24	54.5	98	A 7.47/40/212 V 7.40/49/61
10:08	6.1	59.8	100	A 7.47/40/211 V 7.40/49/61
10:11	5.99	60	102	A 7.47/40/211 V 7.41/49/61
10:14	5.99	60	103	A 7.47/40/210 V 7.40/49/61
10:17	5.99	60	104	A 7.47/41/210 V 7.40/50/60
10:20	5.99	60.9	105	A 7.47/41/211 V 7.41/50/60
10:23		61.4	101	A 7.47/41/211 V 7.40/50/61
10:26		61.8	102	A 7.48/41/210 V 7.41/50/60
10:30		61.9	102	A 7.47/42/211 V 7.40/51/60
10:33		62.4	106	A 7.50/38/213 V 7.42/49/59
10:35		61.5	101	A 7.49/40/208 V 7.43/48/58

10:46		56.7	99	A 7.57/33/212 V 7.52/38/82
10:56		49.5	99	A 7.63/28/214 V 7.56/34/61
11:09		48	100	A 7.63/28/214 V 7.58/33/60
11:11		48	100	A 7.55/34/113 Off ECMO V 7.55/37/43
11:17		45	99	
11:26		45	98	A 7.52/37/158 On ECMO V 7.51/37/39
11:36		44	98	A 7.49/37/132 V 7.49/37/44
11:48		44	99	A 7.47/37/98 V 7.50/36/36
11:58		43	95	A 7.49/37/66 V 7.52/35/36
12:09		42	96	A 7.49/37/66 V 7.51/36/38
12:21		42	95	A 7.48/38/175 V 7.52/36/39
12:32		42	96	A 7.47/39/144 V 7.51/37/40
12:39		42	93	A 7.47/39/123 V 7.51/37/39

12:58		42	96	Saline into lungs ECMO off
1:00		46	58	
1:07		46	60	
1:15		46	60	
1:26		48	58	A 7.45/35/157 V 7.44/40/37
1:30		48	60	
1:45		46	95	On ECMO
1:42				
1:52		47	95	A 7.44/35/158 V 7.44/39/37
2:00		46	94	flow 0.51 V 7.44/40/37
2:10		46	82	A 7.42/36/222 V 7.42/42/36 Arterial Blood 7.50/31/164
2:17		47	144	flow 0.42
2:30				Sensor out - animal moved

Table 6: ECMO Study

Example 7 - ECMO Study:

ECMO was administered to a pig as described above, and a Neotrend (TM) sensor was inserted in the upper fornix of the pig's left eye, with the sensor

results as shown in Table 7 below.

Time	pH	pCO_2	pO_2	Comments, Blood Gases Arterial, Venous
11:26	6.8	21	93	A 7.44/42/515 V 7.45/41+47
11:32	6.59	21	163	A 7.46/42/515 V 7.46/42/41
11:47	6.53	22	171	A 7.46/431518 V 7.46/41/39
11:42	6.56	24	146	A 7.45/43/516 V 7.47/42/37
11:47	6.79	26	120	A 7.42/49/440 V 7.45/44/36
11:52	7.09	27	106	A 7.41/51/437 V 7.44/46/35
12:02	7.47	28	95	A 7.51/39/345 V 7.44/47/36
12:10	7.62	28	95	A 7.51/391340 7.44/48/36
12:15	7.65	28	96	A 7.51/39/335 V 7.44/48/36 Sensor kinked during animal movement

Table 7: ECMO Study

It will be apparent from the foregoing that while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WHAT IS CLAIMED IS:

1. A method of measuring at least one parameter of a patient's tissue, the method comprising:

providing a tissue parameter catheter sensor for sensing at least one parameter of the patient's tissue, the tissue parameter sensing catheter including an elongated tube having a distal portion with at least one sensor for measuring at least one parameter of the patient's tissue, said tissue parameter catheter sensor generating a signal indicative of said at least one parameter;

inserting the distal portion of the tissue parameter catheter sensor in the fornix of the patient's eye in immediate contact with the conjunctiva of the patient's eye; and

receiving said signal indicative of said at least one parameter and displaying an indication of said at least one parameter based upon said signal.

2. The method of Claim 1, wherein said tissue parameter catheter sensor senses a plurality of parameters of the patient's tissue.

3. The method of Claim 1, wherein said tissue parameter catheter sensor senses oxygen, carbon dioxide, and pH.

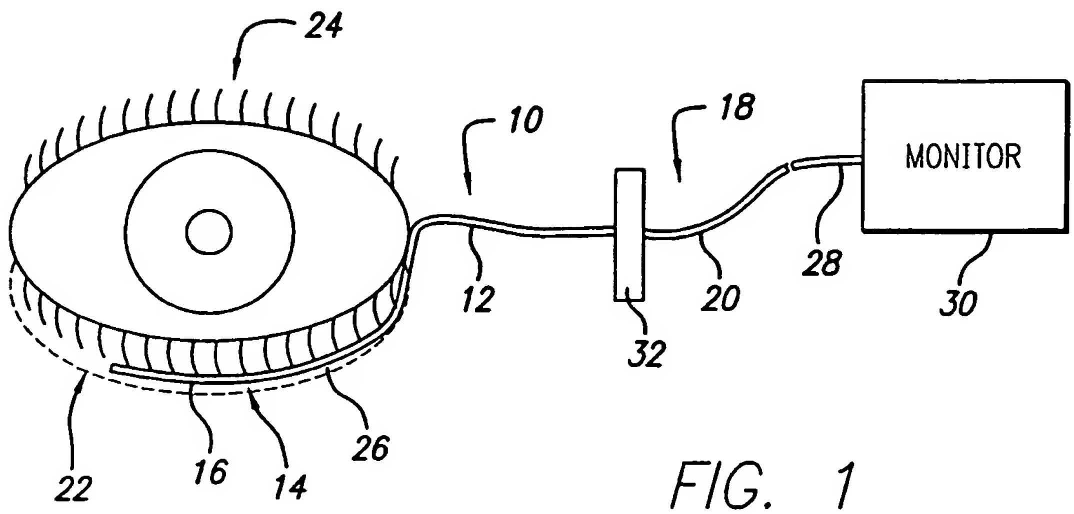

24
10
18
MONITOR
12
20
28
30
32
22
16
14
26

FIG. 1

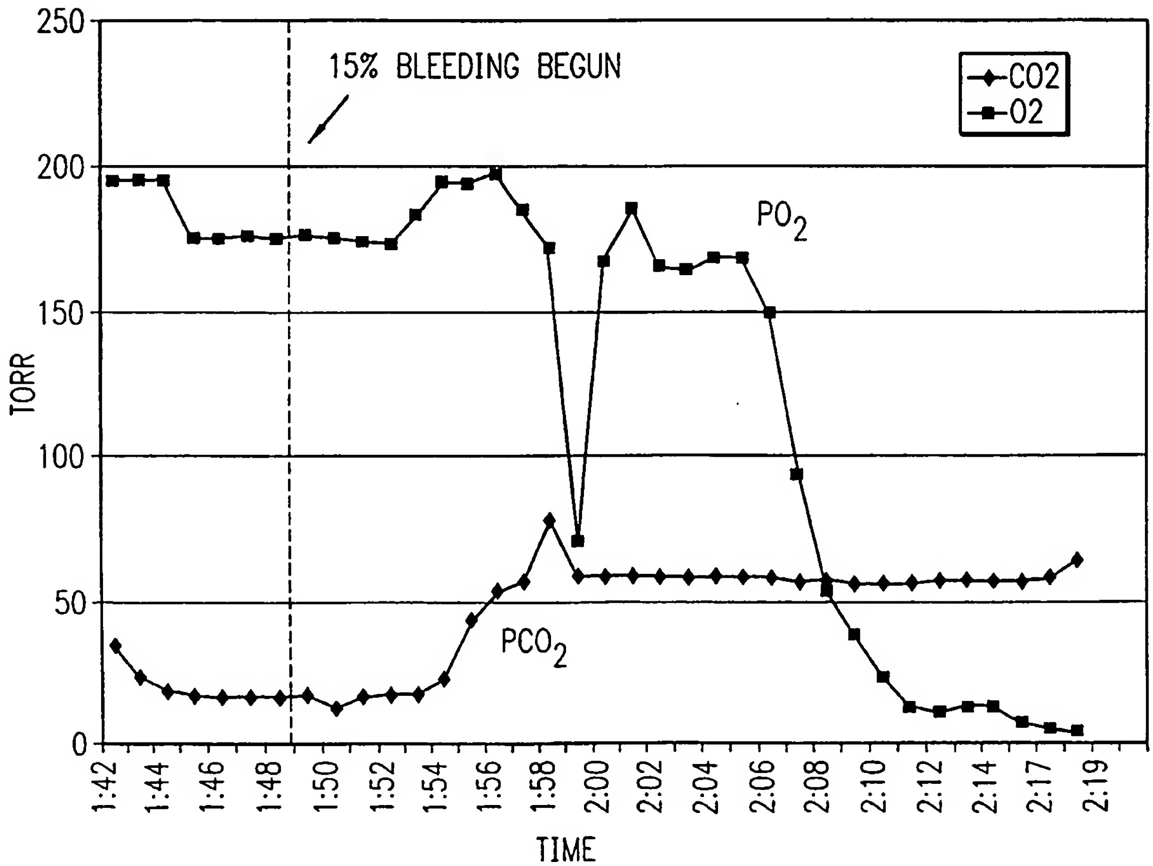
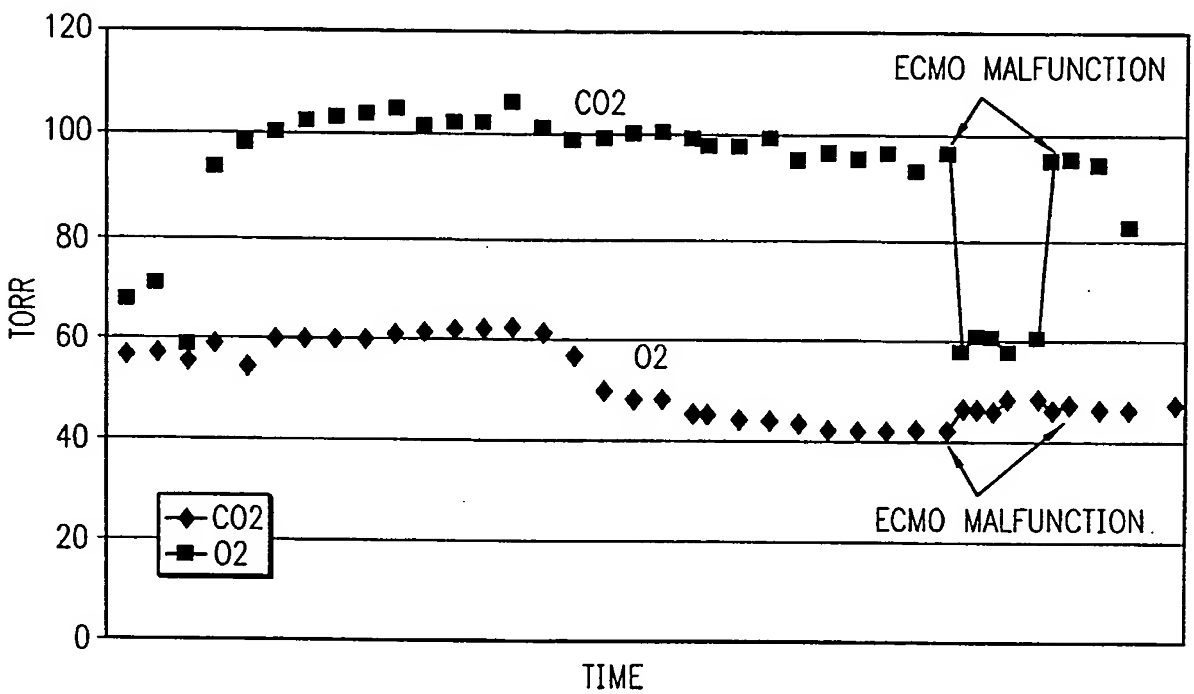

15% BLEEDING BEGUN
CO2
O2
PO_2
PCO_2
TORR
TIME
250
200
150
100
50
0
1:42
1:44
1:46
1:48
1:50
1:52
1:54
1:56
1:58
2:00
2:02
2:04
2:06
2:08
2:10
2:12
2:14
2:17
2:19

FIG. 2

FIG. 3


120
100
80
60
40
20
0
TORR
TIME
CO2
O2
ECMO MALFUNCTION
ECMO MALFUNCTION
CO2
O2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/02897

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 5/00
US CL :600/364
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/364, 309, 362, 365

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	US 6,120,460 A (ABREU) 19 September 2000, column 13, line 48 - column 15, line 9; column 88, line 26 - column 92, line 56.	1-3
X	Isenberg, S.J. et al., "The transconjunctival oxygen monitor," American Journal of Ophthalmology, vol. 95, pp. 803 - 806, 1983.	1, 2

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
07 MARCH 2001	18 APR 2001

Name and mailing address of the ISA/US	Authorized officer
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